



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,258	10/07/2003	Francesco Orlandi	51637/76	3122

23838 7590 08/12/2005

KENYON & KENYON
1500 K STREET NW
SUITE 700
WASHINGTON, DC 20005

EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/679,258

Applicant(s)

ORLANDI ET AL.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>19 May 2005</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

DETAILED ACTION

Applicants' arguments, filed 16 May 2005, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-38 are currently pending.

Information Disclosure Statement

The Information Disclosure Statement filed 19 May 2005 has been considered. A signed copy of PTO Form 1449 is included with this Office Action.

Claim Objections

Claims 1, 6, and 28-30 are objected to because of the following informalities: The claims recite "*a priori*". This should be italicized, as it is in the third lines of claim 1 and 6. However, in line 14 of claim 1, line 16 of claim 6, line 9 of claim 28, line 10 of claim 29, and line 11 of claim 30 "*a priori*" is not italicized. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1631

Claims 1-5, 7-27, 31, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

Claim 1 recite “wherein the BPD/OFD ratio and the at least one secondary marker measurement are determined at a same trimester of pregnancy”. However, the support given by Applicant for this limitation is not found. There is no page 42 in the specification as filed. The Examiner looked to paragraph 42, and no support was found there either. The specification fails to teach such a limitation. The specification states only that “preferably, such measurements are taken during the first trimester” (page 5, lines 5-6). This is in reference to the BPD/OFD measurement only and not to the measurements being taken together in the first trimester. As such, this is new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1631

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 28-30, and 33-38 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,573,103 B1 (Wald), in view of Stempfle et al. (Pediatric Radiology (1999) Vol. 29, pages 682-688), for the reasons set forth in the previous Office Action.

Response to Applicant's Arguments

1. Applicant argues that "claim 1 recites that the OFD/BPD (*BPD/OFD*) ratio and the secondary marker measurement are determined at the same trimester of pregnancy. The very point of Wald is to take markers from two different stages of pregnancy. See Abstract".

While this may be true for claim 1 as presently amended, claims 6, 28-30, and 33-38 do not contain such a limitation. The only limitation is on the BPD/OFD ratio, which is taken at the first trimester. As such, Wald in view of Stempfle still makes obvious the claims for the reasons previously presented.

Art Unit: 1631

2. Applicant argues that “with respect to claim 6, this claim recites that the OFD/BPD (*BPD/OFD*) is taken during the first trimester of pregnancy. As the Examiner recognizes, Wald does not teach or suggest measuring OFD/BPD (*BPD/OFD*) ratio. Furthermore, Stempfle does not make up for this deficiency”.

This is not persuasive. It is noted that Wald is taken in view of Stempfle and therefore, it is the Stempfle reference that is relied upon to teach the BPD/OFD ratio measurement, as stated at page 8, line 18 to page 9, line 2 of the previous Office Action. Stempfle clearly teaches BPD/OFD ultrasonographic measurements. Wald teaches ultrasonographic measurements in the first trimester, as previously stated. (see column 2, lines 17-18). As such, the Examiner maintains that Wald in view of Stempfle makes obvious the claims.

3. Applicant argues that “Stempfle does not indicate that these skeletal signs justify chorionic villus sampling (CVS)”.

This is not persuasive, as the claims contain no such limitations.

4. Applicant lastly argues that “there is no evidence in Stempfle that measuring the OFD/BPD (*BPD/ODF*) ratio during the first trimester is a reliable indicator of trisomy 18”.

This is not persuasive, as claim 36 is drawn to a method of claim 35 (which depends from claim 33, which depends from claim 6) wherein the trisomic abnormality is Down Syndrome, trisomy 13, or trisomy 18. Wald and Stempfle teach Down syndrome and therefore anticipate the claim.

Rejection of claims 1-5, 7-27, 31, and 32 over 35 USC 103(a) have been withdrawn in view of the amendment. However, it is noted that the amendment contains new matter, as stated

Art Unit: 1631

above. Applicant is cautioned that the removal of the new limitations may result in re-instatement of the rejections previously made under 35 USC 103(a).

No claims are allowed.

Conclusion

The rejections over 35 USC 112, 1st paragraph-enablement have been withdrawn in view of the amendments to the claims incorporating the limitation of “wherein the fetal abnormality is a craniofacial abnormality, a chromosomal abnormality, of a developmental central nervous system abnormality”.

The rejections over 35 USC 112, 2nd paragraph have been withdrawn in view of the amendments to the claims.

The rejections of claims 1-5, 7-27, 31, and 32 over 35 USC 103(a) have been withdrawn in view of the amendments to the claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1631

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

August 3, 2005
Lori A. Clow, Ph.D.
Art Unit 1631

Lori A. Clow

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
8/5/05